

# Notice of Allowability

Application No.

10/044,441

Examiner

Brad Y. Chin

Applicant(s)

GONZALEZ ET AL.

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## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/3/2005.
2. ☒ The allowed claim(s) is/are 1-6 and 8.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

DETAILED ACTION

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel Pastirik on 16 August 2005.

The application has been amended as follows:

In the claims:

Claim 1, line 1, please delete -- (Previously Presented) -- and in its place insert--  
(Currently Amended) --

Claim 1, line 12, after "reader", please insert -- with the sterilization sensor therein and --

***Reasons for Allowance***

2. Claims 1-6 and 8 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: Applicant's claims 1-5, include the limitations for an apparatus and a method for determining the efficacy of a sterilization process and communicating the determination to a remote location, wherein a reader is adapted for inclusion within the pack of goods to be sterilized. The reader is adapted to receive the sterilization sensor, which undergoes an optical change; an illumination source for illuminating the sterilization sensor; a first color sensor for evaluating the illuminated sterilization sensor; an interpretation circuit; and a communication circuit. Kirckof et. al. teach machine readable sterilization indicators for monitoring articles to be sterilized, which includes a

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reader comprising an illumination source, a detector or first color sensor, an interpretation circuit, and a communication circuit. Kirckof et. al. describes the reader as a moving beam scanner, a handheld scanner, fixed mount scanners, and laser and solid state imagers – all external devices, independent of the sterilization indicators. Kirckof et. al. fails to teach that the sterilization sensor is received in the reader, and further fails to teach that the reader is adapted for inclusion within packs of goods to be sterilized. Joslyn teaches a sterilization analyzer, comprising a sterilization indicator, a reader, an interpretation circuit, and a communication circuit, that upon subjecting a package to sterilizing conditions interrogates the reader without opening the package to learn whether particular sterilizing conditions have been met. Joslyn fails to teach that the sterilization indicator undergoes an optical change when exposed to an efficacious sterilization process, nor teaches placing the reader with the sterilization sensor and the supplemental components inside the package of goods. Wang et. al. teach a system and method for monitoring concentrations of sterilant within a sterilization apparatus, comprising a sterilization reader adapted to receive a sterilization sensor, an interpretation circuit, and a communication circuit. The reader is further adapted for inclusion within packs of goods to be sterilized. Wang et. al. fails to provide an illumination source and a first color sensor. None of the references teach the claimed limitations nor would it have been obvious to combine references to achieve the claimed inventive subject matter. Although Wang et. al. teaches a reader adapted for inclusion within packs of goods, it would not have been obvious, without destroying Kirckof et. al. or Wang et. al., to combine the references to teach the claimed limitations of Applicant's invention for providing a reader adapted to receive the sterilization indicator with an illumination source, first color sensor, interpretation circuit, and a communication circuit, all included within the packs of goods to be sterilized.

Claims 6 and 8 include the limitations for the method, wherein the reader, which comprises an illumination source, color sensor, interpretation circuit, and communication circuit, is adapted for inclusion within the pack of goods to be sterilized. Kirckof et. al. teach machine readable sterilization indicators for monitoring articles to be sterilized, which includes a reader comprising an illumination source, a detector or first color sensor, an interpretation circuit, and a communication circuit. Kirckof et. al. describes the reader as a moving beam scanner, a handheld scanner, fixed mount scanners, and laser and solid state imagers – all external devices, independent of the sterilization indicators. Kirckof et. al. fails to teach that the sterilization sensor is received in the reader, and further fails to teach that the reader is adapted for inclusion within packs of goods to be sterilized. Joslyn teaches a sterilization analyzer, comprising a sterilization indicator, a reader, an interpretation circuit, and a communication circuit, that upon subjecting a package to sterilizing conditions interrogates the reader without opening the package to learn whether particular sterilizing conditions have been met. Joslyn fails to teach that the sterilization indicator undergoes an optical change when exposed to an efficacious sterilization process, nor teaches placing the reader with the sterilization sensor and the supplemental components inside the package of goods. Wang et. al. teach a system and method for monitoring concentrations of sterilant within a sterilization apparatus, comprising a sterilization reader adapted to receive a sterilization sensor, an interpretation circuit, and a communication circuit. The reader is further adapted for inclusion within packs of goods to be sterilized. Wang et. al. fails to provide an illumination source and a first color sensor. None of the references teach the claimed limitations nor would it have been obvious to combine references to achieve the claimed inventive subject matter. Although Wang et. al. teaches a reader adapted for inclusion within packs of goods, it would not have been obvious, without destroying Kirckof et. al. or Wang et. al., to combine the references to teach the claimed

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limitations of Applicant's invention for providing a reader adapted to receive the sterilization indicator with an illumination source, first color sensor, interpretation circuit, and a communication circuit, all included within the packs of goods to be sterilized.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Y. Chin whose telephone number is 571-272-2071. The examiner can normally be reached on Monday – Friday, 8:00 A.M. – 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sun (John) Kim, can be reached at 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

byc  
August 11, 2005

  
**JOHN KIM**  
**SUPERVISORY PATENT EXAMINER**